

**Maryland Board of Pharmacy
Public Minutes
September 19, 2007**

Officers Present: Donald Taylor, President; and Dave Chason, Secretary

Commissioners: Cynthia Anderson, Lynette Bradley-Baker,
Harry Finke, Jr., Mayer Handelman, Lenna Israbian-Jamgochian, Alland Leandre,
Rodney Taylor, and Reid Zimmer

Commissioner(s) Absent: Michael Souranis, Treasurer and Margie A. Bonnett

Board Staff: LaVerne Naesea, Executive Director; Patricia Gaither, Administration and Public Support Manager; Summar Goodman, Public Information Officer; Tamarra Banks, MIS Manager; and Colin Eversley, Compliance Investigator.

Board Counsel: Linda Bethman

Guests: Richard Mainzer, Woodhaven; Jeanne Furman, Mercy Medical Center; Ron Nicholson, VetCentric; Howard Schiff, MPhA; Connie Baker, Venable; James Martin, Advanced Pharmacy; Betsy Evers, Manor Care; Anthony Hopkins, Manor Care; Jim Moncrief, Advanced Pharmacy; Jay Krosvick, Woodhaven; Tony Tommasello, PEAC; Dave Barr, Advanced Pharmacy; Justin Coyle, Walgreens; Cyndi Meissel, Allied Pharmacy Services; Larry Kelley, Woodhaven; Georgette Zoltani, Division of Drug Control; Fred Evans, Division of Drug Control; Rhiannon Fitzsimmons, Johns Hopkins; Melvin Rubin, Stephen Riggin, CVS; Gil Genn, MACDS; Chandra Mouli, Division of Drug Control; Sharon Bloem, Office of Senator Paula Hollinger; Senator Paula Hollinger, Lorenzo Bellamy, Alexander and Cleaver; Cecilia Baker, Target; and Amanda Jade, Howard University.

I. Introduction/Recusals- Members of the Board with a conflict of interest relating to any item on the agenda were asked to notify the Board at this time. There were no recusals.

II. Approval of Minutes, August 22, 2007

Page 2- under "Inspection Transition Plan", 1st sentence, insert the word "Drug" after the word "of".

Page 2 – under 2nd Board Action – 2nd paragraph – Delete the last sentence, "Also, a copy of the inspection form will be sent to all permit holders."

Page 9 – typo "leave of absences" delete the letter (s) from the word absence

Page 6- under “News Article” – 3rd sentence, after Cynthia Anderson insert “represented the Pharmacy”

Page 10 G- Remove “tight” from the first sentence.

Motion: Alland Leandre moved to accept the minutes as amended. Reid Zimmer seconded the motion.

Board Action: The Board voted unanimously to approve the minutes as amended.

III. President/Executive Committee Report – Donald Taylor

Introduction of New Board Members

Mr. Taylor introduced new Board Commissioner Lynette Bradley-Baker, who has been appointed to the Board’s At-Large position.

Tamper Proof Prescriptions

Mr. Taylor informed the Board that the State Medicaid Program will be conducting inspections for compliance with the new CMS ruling requiring tamper-resistant prescription pads. A list containing contact information was made available.

Committee Appointments

Mr. Taylor announced that new Committee assignments have been completed. Committee meeting dates have been changed. Commissioners have been notified of their committee assignments. Recommended meeting start times are 9 am and 1 pm.

Action Item: Alicia was asked to consult with Committee Chairs regarding exact starting times of meetings.

DHMH Prescription Drug Purchasing Protocol

The Department of Health and Mental Hygiene (DHMH) Office of Epidemiology and Disease Control (EDCP) recently changed its process for purchasing vaccines and related medications. HO§12-602(e) provides that a distribution permit holder may distribute prescription drugs to an authorized prescriber, pharmacy or distribution permit holder or any other person approved by the Board. Since EDCP does not have an authorized prescriber or permit holder eligible to receive drug distributions, it has requested that it be approved by the Board to receive necessary drugs. Prior to considering approval of the request, the Board required EDCP to submit a protocol that outlines EDCP’s procedures for ordering, storing, dispensing and inventory control of drugs that it would receive. The first draft of a protocol has been submitted for review. The full Board will review the final protocol for consideration of approval.

IV. Executive Director's Report – LaVerne Naesea

Division of Drug Control – Transition Plan Update

Ms. Naesea welcomed new Board member Lynette Bradley-Baker. Ms. Naesea reported that Secretary Colmer has approved and signed the Inspection Transition Plan submitted by the Board of Pharmacy and the Division of Drug Control. The Board staff will begin recruiting for a pharmacist inspector and highly qualified technicians to perform the inspections. Ms. Naesea stated that the Board would work with Human Resources to create a new position description for the inspectors. The Transition Plan would begin implementation at the end of October. Initially, the positions would be contractual.

Division of Drug Control Statistics

Ms. Naesea provided the monthly report from the Division of Drug Control: There were 80 annual pharmacy inspections; 23 opening inspections; and 19 closing inspections performed during the month of August.

Appreciation Dinner

Ms. Naesea announced that the Board would be hosting an Appreciation Dinner for prior Board members October 17th at Liberatores' Restaurant at 6:00 pm. The public is invited. For further information contact Summar Goodman, at the Board's Office 410-764-4755.

Board Retreat

The Board's Retreat is projected for January 2008. There will be a short public meeting. The meeting location and schedule will be published in the Maryland Register and on the Board's website.

V. PEAC (Pharmacist Education and Assistance Committee) – Tony Tommassello, Ph.D.

Dr. Tommassello reported that PEAC's caseload consists of 11 cases, of which two (2) are pharmacy students and one (1) is a technician. PEAC received 34 urine samples with no positive results. Dr. Tommassello reported that PEAC has one new case under contract. He invited meeting participants to attend PEAC's annual seminar on Thursday, October 18th at Riderwood Village in Silver Spring, Maryland. The seminar is entitled "The Bottom Line on Addiction and Recovery: Practical Lessons and Guidance for Pharmacists, Colleagues and Employers". Dr. Tommassello reported on the methods used by PEAC to distribute the "Duty to Report" poster.

VI. Legislation and Regulation Manager – Anna Jeffers

A. Legislation

The Drug Therapy Management legislative proposal has been submitted to the Office of Governmental Affairs. The Board has requested that the proposal be sponsored by the Department of Health and Mental Hygiene. As an alternative plan, Anna Jeffers will recruit legislative sponsors.

B. Regulations Update

Pharmacy Technicians Regulations and Reinstatement

The Pharmacy Technician regulation re-proposal should be published in the Maryland Register September 28 2007.

Sterile Pharmaceutical Compounding Regulations

The Sterile Pharmaceutical Compounding Notice of Final Action was published on August 31, 2007. The effective date is September 10, 2007.

Wholesale Prescription Drug or Device Distributors Regulations

The final recommendations of the August 13, 2007 Wholesale Distributor SB 759 Workgroup have been submitted to the Board. The Practice and Licensing Committees are reviewing the recommendations which will be submitted for final Board approval at the October meeting.

VIII. Administration and Public Support – Patricia Gaither

A. Personnel Update

Ms. Gaither reported that she has received approval of the Board's freeze exemption request for the Health Occupation Investigator position. She plans to move forward with a conversion from a contract to a permanent position.

Three (3) resumes have been received for the Pharmacist Compliance Officer position. DHMH/Human Resources Department has reviewed the resumes. The resumes have been submitted to the Executive Committee for review.

A Pharmacist III and Healthcare Facilities Surveyor I & II positions have been requested under a contractual status. In total, five (5) positions have been requested: one Pharmacist Inspector; three (3) Healthcare Facilities Surveyor I (Pharmacy Technician) positions and one Healthcare Facilities Surveyor II (Pharmacist Technician) position. All of the positions are under evaluation to determine the appropriate State salary and grade.

B. Public Information Officer Report – Summar Goodman

Emergency Preparedness Volunteer Training Seminar

Ms. Goodman reported on the upcoming Emergency Preparedness Training Seminar that will be held at the Radisson Hotel at the Village of Cross Keys, Sunday, October 28, 2007, from 7:30 am until 1:00 pm. Staff from the Board will be taking picture IDs for badges. A representative from DHMH is responsible for making badges for all Boards. Ms. Goodman stated that “flyers” have been mailed to all Maryland pharmacists and an announcement about the Seminar has been posted on the Board’s website. Interested pharmacists may still register.

Action Item: Summar Goodman to provide updated information regarding the Emergency Preparedness Volunteer Badges on the Board’s website.

IX. Management Information Services – Tamarra Banks

Board of Pharmacy Database

Because of contractual changes, the submission for the last phase of the Memorandum of Understanding (MOU) was delayed. The Board and the Towson University have agreed verbally on language for the last phase of the MOU. Ms. Banks expects that submission of the MOU to the State Contracts Division will occur by the end of this week.

Pharmacist Online Renewal Database

Equipment failure created the need for staff to manually enter pharmacists’ online renewal data into the mainframe computer and the mail log. Ms. Banks explained that the problem has now been repaired. MIS Staff is currently up-loading the remaining records into the mainframe.

Division of Drug Control/Inspections

Inspectors Howard Minster and Peter Smith, from the Division of Drug Control, had experienced problems with uploading inspection information into the Board’s database from their laptop computers from the end of August to the present. Ms. Banks reported that the problem was caused because the MIS Unit installed a new file server and added a new version of MS Access database. The unit is still working with the Division of Drug Control to update pharmacists info into inspectors laptops. MIS expects to resolve any related issues next week by manually placing files or other software modifications on their laptops.

Vanessa Thomas-Gray, Compliance Investigator, has been entering paper inspections manually. She has requested assistance from the MIS unit in interpreting submitted inspection data.

Establishment Database

The Licensing Unit met with the MIS unit on September 6th to discuss the process for renewing establishment permits. A mechanism for allowing online payments using a credit card was not developed because the Board will be testing the new database systems for on-line renewals. It was determined that the process may become cumbersome if several new initiatives are introduced at the same time. The system will allow use of credit cards for payment in FY 2009.

Contracts

The Board staff is in negotiations for a contract with Maryland Archives and/or Spring Grove State Hospital as host sites for Disaster Recovery server locations.

Emergency Preparedness

A new MDBOP Updates email account has been established and is available to the Emergency Preparedness Task Force for the transmittal of upcoming events. The test of the system sent 3762 emails using the Board's new Blast email program. The account is called MDBOP Updates@dhhm.state.md.us. Returned emails indicate accounts that no longer exist or contain mistyped email addresses.

Internet/Website

Ms. Banks provided statistical information concerning the number of emails for:

January: 336	February: 271	March: 295	April: 264
May: 374	June: 341	July: 356	August: 303

Webpage updates/New

Ms. Banks reported that the Board will be launching a new Verification page that allows for the display of licensee and permit holder status by license number and last name searches.

Secured Web Site

MIS is awaiting final approval from the Board on the types of information to be placed on the secured Board member site only.

X. Committee Reports

A. Practice Committee – Dave Chason

1. Constituent Questions and Responses

- a. Constance H. Baker, Venable, LLP wrote the Board of Pharmacy to ask whether Advanced Pharmacy's AP PassPort automated, remotely monitored medication dispensing center complies with Maryland laws and regulations.

Mayer Handelman recused himself from the discussion and voting regarding the Advanced Pharmacy Remote Automated Med System.

The Practice Committee recommended to the Board that the letter indicate that the device is not compliant because there is not a final check by a pharmacist of repackaged medications.

Motion: Alland Leandre moved to accept the Practice Committee's letter as written. Harry Finke, Jr. seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

- b. Leah T. Bowden, Administrator, Potomac Valley Nursing and Wellness Center wrote the Board concerning whether Advanced Pharmacy's AP PassPort automated, remotely monitored medication dispensing center complies with Maryland laws and regulations.

The Practice Committee recommended that the same response sent to Constance Baker be applied to this question.

Motion: Cynthia Anderson moved to accept the Practice Committee's letter as written. Harry Finke, Jr. seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

- c. Denise Dimmitt, pharmacy technician, wrote the Board concerning pharmacy automation and counting equipment questions.

Ms. Dimmitt asked whether there are any regulations concerning mixing lot numbers of the same product in a retail or hospital pharmacy automation storage compartment.

The Practice Committee response was that there are no specific regulations concerning mixing lot numbers in an automated storage compartment. The lot numbers may be

mixed as long as all lots and expirations are documented according to the date on the storage compartment and if the expiration dates of the shortest dated item is at least a year from the prescription fill date. Ideally, any restocking process should minimize the mixing of different expiration dates and lot numbers in a cell since the expiration of the shortest dated item will be in the software and/or on the label of the cell. If there is a recall, all the medications within the compartment containing the affected lot(s) must be removed from the automated storage compartment and sequestered as recalled.

Ms. Dimmitt also asked about labeling requirements for such storage compartments of each drug. Can the labeling and tracking of lot and expiration numbers be done using a software system or does it need to physically be on the compartment?

The Practice Committee responded that there is no reference to this in Maryland regulations. The recommendation is to place a label on the cell containing the drug as a constant reminder to the staff regarding the expiration date and to facilitate inspection as part of the departmental quality assurance program or Board of Pharmacy inspection process. There are no specific regulations that address labeling of storage compartments. The permit holder is responsible for complying with the requirements for automated medication system(s), which includes a comprehensive program of quality assurance. See The Code of Maryland Regulations (COMAR) 10.34.28.01 - .13

Cynthia Anderson suggested that the word “additionally” be added after the word “cell” in the second paragraph.

It was suggested that the word “however” be deleted before “then all the medications....”

Motion: Rodney Taylor moved to accept the letter as amended. Alland Leandre seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

B. Licensing Committee – LaVerne Naesea for Michael Souranis

Ms. Naesea reported for Mr. Souranis in his absence. The Licensing Committee’s meeting has been changed to the fourth Wednesday of the month. Ms. Naesea also stated that NABP has cancelled current scheduling of the NAPLEX examination because the integrity of the exam has been compromised.

Ms. Naesea provided the Licensing Report for the Month of August.

Establishments:

New:	August 2007	August 2006
	20	New: 23
Distributor – In State	1	1
Distributor – Out of State	11	8

Resident Pharmacy	2	4
Non-Resident Pharmacy	5	4
Pharmacy w/Waiver	1	2

Closed:		
Distributor – In State	5	2
Distributor – Out of State	1	
Pharmacy	2	1
Non-Resident Pharmacy	1	
Pharmacy w/Waiver	0	

C. Long Term Care Task Force - Mayer Handelman

Assisted Living/Pharmacy Review

Ms. Jeffers provided the Long Term Care Task Force report for Mr. Handelman. Nicki Brandt, Pharm D. spoke at the September Task Force meeting about the importance of frequent pharmacist reviews of patient’s medications. As with LTC residents, assisted living residents are often medically fragile. A quarterly review of medication regimens is the best timeframe she considers adequate to insure patient safety.

HB 837 Workgroup – Contract Pharmacy

The Workgroup finished reviewing all the comments submitted to the Office of Health Care Quality’s proposed COMAR 10.07.02 regulations entitled “Comprehensive Care Facilities and Extended Care Facilities.” Revised regulations will be prepared based on comments received and should be available for public comment in the Spring. This will be followed by re-publication and another comment period.

Board of Pharmacy Statement on LOA in Long Term Care

Ms. Jeffers stated that the Office of Health Care Quality (OHCQ) anticipates that they will revise their regulations to remove the prohibition of a nurse giving medications to residents for short leaves of absence. The Board may submit official comments when OHCQ promulgates the revisions.

The Task Force Meetings will change from a monthly to quarterly schedule.

| *The Review of the Board of Pharmacy LTC Pharmacy Inspection Form was postponed until December’s Long Term Care meeting.*

Tamper Proof Prescription Pads

The status of the CMS ruling on Tamper Proof Prescription Pads effective October 1, 2007 has not changed. Federal legislation has been introduced to delay implementation for one year.

D. Disciplinary Committee – Mayer Handelman

Mr. Handelman reported that the Disciplinary Committee would be very busy with the addition of the requirement to monitor pharmacy technicians. He also reported that Rodney Taylor and Leanna Israbian-Jamgochian would be reviewing pharmacy inspection reports to expedite the work of the Committee.

Action Item: The Disciplinary Committee will create a format to post information about stolen prescription pads on the Board’s website and will establish a time frame to have that information posted on the website.

XI. Informational – Donald Taylor

Donald Taylor shared with the Board several current informational pharmacy issues.

1. Support for doctor-filled prescriptions – There was a nationwide poll indicating three (3) out of four (4) Americans supported having their prescriptions filled by their doctors at the point-of-care citing: convenience, saving time, and quality of care which they thought helped them manage their health.
2. US House currently has 16 bills focusing on “cheap” medicine. All groups are seeking affordable medicine. Several bills include importation provisions.
3. DMEPOS Competitive Bidding & Accreditation Process. Suppliers of DME (durable medical equipment) must be accredited by 2009. There are 150,000 suppliers which include pharmacies. There are ten (10) CMS approved accrediting organizations. Medicare will not reimburse agencies that are not accredited. Part B drug suppliers do not have to be accredited. CMS will approve only the number of suppliers in a given area to meet the needs of the beneficiaries. The payment will be based on the mean price for each item from the submitted bids.
4. Tamper Resistant Rx Pads – CMS deadline 10-1-2007 – All pads must contain at least one (1) of the following: One (1) or more industry-recognized features designed to prevent unauthorized copying of a completed or blank Rx form. One (1) or more industry-recognized features designed to prevent the erasure or modification of information written by the prescriber. One (1) or more industry-recognized features designed to prevent the use of counterfeit prescription forms. After 10-1-2008, all of the above rules must apply. The rule does not apply to electronic, verbal or faxed prescriptions or for

prescriptions used in designated institutional or clinical settings. Physicians still use other pads as long as a verbal, faxed, electronic, or complaint prescription is provided within 72 hours. At this time 76 health care organizations have urged Secretary Leavitt to delay the implementation date.

5. CMS final rule on Average Manufacturer Price (AMP) for the Medicaid program. The payment is below cost for many drugs and favors brand name medications over generics although generics have been shown to save the program money. H.R.31.40 (Saving our Community Pharmacies Act of 2007) has been submitted by Representatives. Boyda & Emerson to replace AMP with RAC (retail acquisition cost)
6. 2003 Medicare Modernization Act (MMA) Statement by secretary Leavitt. Proposed rule – after 1-1-2009, Controlled Substance Prescriptions can NOT be sent via computer generated faxes. (May still be sent by stand-alone fax machines.)

Cynthia Anderson moved to adjourn the Public Meeting at 10:35 am. Immediately thereafter, Donald Taylor convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session. Margie Anne Bonnett attended the Administrative Session.